

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0391]

**Draft Guidance for Industry and Food and Drug Administration Staff;
Functional Indications for Implantable Cardioverter Defibrillators;
Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

DDM
Orig. Reg. Date: 10-5-05
Publication Date: 10-6-05
Case No.: D. Hawkins

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Functional Indications for Implantable Cardioverter Defibrillators.” Many implantable cardioverter defibrillators (ICDs) currently have a functional indication. This draft guidance is designed to describe ICD functional indications and the types of devices appropriate for the indication; to provide guidance regarding labeling, advertising, and promotion of ICDs with an approved functional indication and cardiac resynchronization therapy defibrillators (CRT/ICDs) with an approved indication that describes the function of the ICD component; and to discuss when to submit an application for an investigational device exemption (IDE) for a study involving a potential new patient population for an ICD with an approved functional indication.

DATES: Submit written or electronic comments on this draft guidance by [*insert date 90 days after date of publication in the Federal Register*].

ADDRESSES: Submit written requests for single copies on a 3.5” diskette of the guidance document entitled “Functional Indications for Implantable

Cardioverter Defibrillators” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For premarket issues: Owen Faris or Megan Moynahan, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8517.

For promotion and advertising issues: Deborah Wolf, Center for Devices and Radiological Health (HFZ-302), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-594-4589.

SUPPLEMENTARY INFORMATION:

I. Background

Prior to June 2000, the indication statement for ICDs included language to describe the types of patients who would benefit from an ICD. If a manufacturer demonstrated in a clinical trial that a new patient population benefited from its ICD, that manufacturer could submit a premarket approval application (PMA) supplement to update its indication statement to include

that new patient population. That manufacturer could then promote its ICD as indicated for the new population. On June 20, 2000, FDA held a public meeting of the Circulatory Systems Devices Panel to introduce the concept of a functional indication. The functional indication describes what the device does and does not explicitly specify as an indicated patient population or expected outcome. FDA presented the functional indication as a least burdensome method of allowing the clinical community to identify the patient populations that would benefit from an ICD. The panel endorsed the functional indication concept for ICDs and, since that time, FDA has approved a functional indication for most manufacturers' ICDs. This guidance document is intended to discuss the intended patient population for ICDs with an approved functional indication and CRT/ICDs with an approved indication that describes the function of the ICD component, labeling, advertising, and promotion of those ICDs and CRT/ICDs, and when to submit an application for an IDE for a study involving a potential new patient population for an ICD with an approved functional indication.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the agency's current thinking on functional indications for ICDs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive "Functional Indications for Implantable Cardioverter Defibrillators" by fax, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the

system. At the second voice prompt, press 1 to order a document. Enter the document number 1304 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

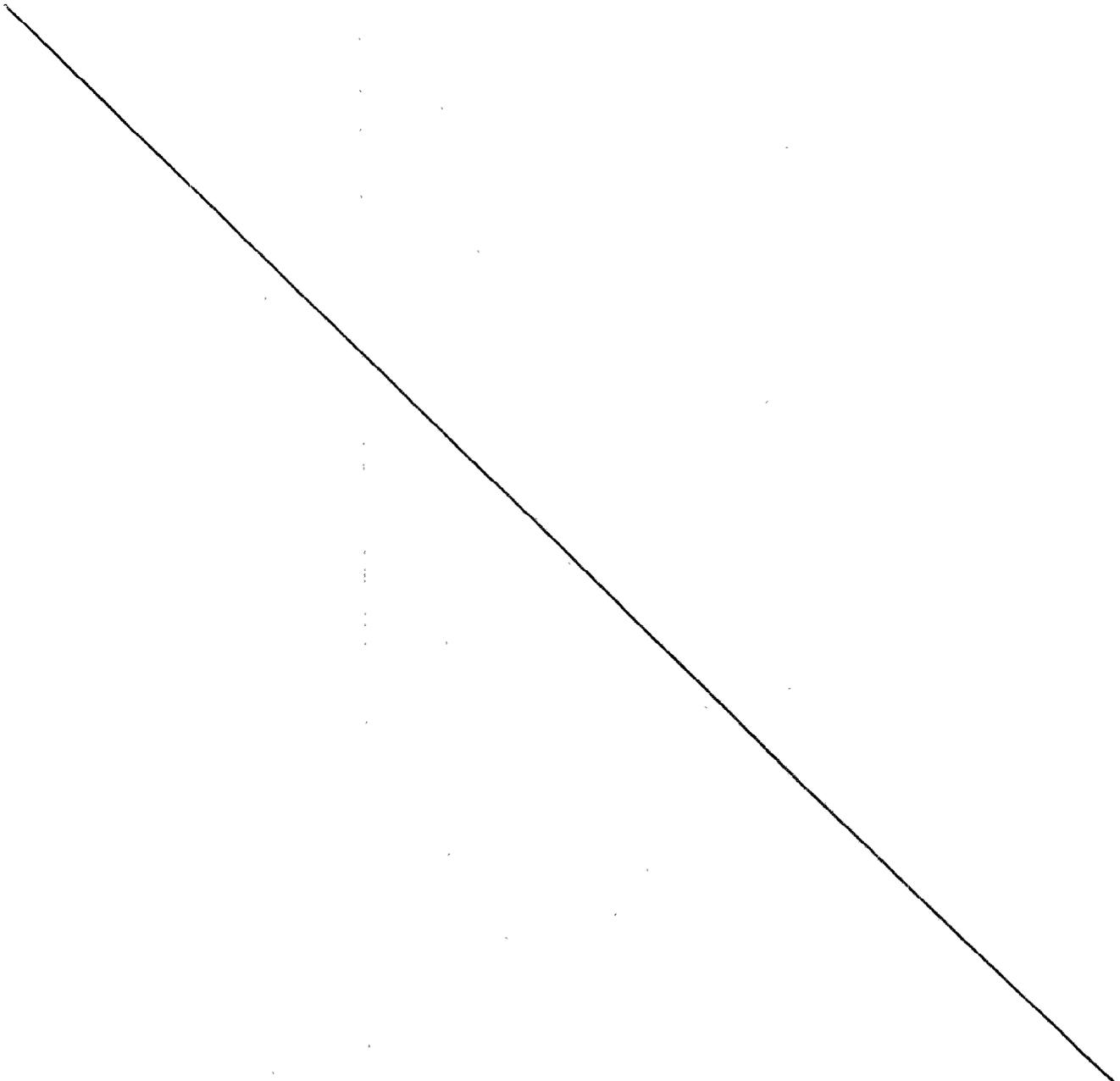
Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing IDEs (21 CFR part 812, OMB control number 0910–0078) and PMAs (21 CFR part 814, OMB control number 0910–0231). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

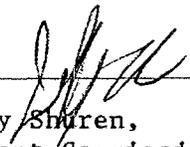
V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document on or before [*insert date 90 days after date of publication in the Federal Register*]. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be



identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 9/29/05
September 29, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL
Dawn P. Hawkins